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BiliSoft Phototherapy System APR 17 2006

510(k) Summary

Submitter Information

Lumitex, Inc.
8443 Dow Circle
Strongsville, OH 44136
Phone : 440-243-8401
Fax : 440-243-8402
Contact Person : Jeff Williams, VP Engineering
Email: jwilliams@lumitex.com
Date Prepared : September 30th, 2005

Device Names

Classification name: Unit, Neonatal Phototherapy
Common Name: Phototherapy light, Bili Light
Trade Name: BiliSoft™ Phototherapy System

Predicate Device Information

The BiliSoft phototherapy System is substantially equivalent to the following, legally marketed products:

- Ohmeda Medical, a division of Datex-Ohmeda– BiliBlanket Plus High Output Phototherapy System
- Natus – neoBLUE LED Phototherapy
- Medela – Bili Phototherapy Unit

Indications for Use

The Bili-Soft Phototherapy System provides light therapy for the treatment of hyperbilirubinemia, commonly know as neonatal jaundice, during the newborn period in the hospital or home setting. The Bili-Soft Phototherapy System emits a narrow band of blue light considered to be the most effective in the treatment of hyperbilirubinemia.

Product Description

The Bili-Soft Phototherapy System is a mobile phototherapy device that delivers high intensity blue light using blue light emitting diodes (LEDs) that transmit light to a fiber optic pad.

The device consists of a light source box and one of two different size fiber optic pads. The light source operates in a single light intensity mode and includes features such as an over temperature indicator with automatic LED shutoff and an hour meter to indicate life. The light source has an automatic universal voltage selection of 90-264 VAC at 47-63 Hz.

Fiber optic pad covers are made of a clear, medical grade, hypoallergenic and latex-free material. The smaller fiber optic pad emits an average output of 35 $\mu W/cm^2/nm$ through a typical snuggly/pad cover, and the larger fiber optic pad emits an average output of 50 $\mu W/cm^2/nm$ through a typical snuggly/pad cover. Disposable fiber optic pad covers are available to help comfortably position the baby on the fiber optic pad and to prevent cross contamination of bodily fluids between infants.

LED's have very little light degradation over their lifetime with proper use and care. During normal operating conditions the device is expected to last for approximately 10,000 hours. Once the LED's have reached the end of their life a replaceable LED module is available for purchase. LED's emit no appreciable energy in the ultraviolet (UV) region of the spectrum, so there is no concern for UV exposure to the infant. In addition, LED's emit no significant energy in the infrared (IR) region of the spectrum; therefore there is no concern for excessive warming of the infant due to IR energy.

Performance Data

Since the treatment of neonatal hyperbilirubinemia with phototherapy is a well establish clinical practice, clinical or animal testing to demonstrate safety and effectiveness is not necessary. The product has been subject to extensive bench testing, and the requirement of 21 CFR 820, Subpart C – Design Controls – were satisfied.

Sterilization Information

The BiliSoft Phototherapy system is not intended to be supplied sterile. Cleaning and disinfecting instructions can be found in the Operation and Maintenance Manual.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 17 2006

Mr. Jeff Williams
Vice President of Engineering
Lumitex, Incorporated
8443 Dow Circle
Strongsville, Ohio 44136

Re: K053568
Trade/Device Name: BiliSoft Phototherapy System
Regulation Number: 880.5700
Regulation Name: Neonatal phototherapy unit
Regulatory Class: II
Product Code: LBI
Dated: March 16, 2006
Received: March 17, 2006

Dear Mr. Williams:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): _____

Device Name: BiliSoft Phototherapy System

Indications for Use:

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Prescription Use X AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[illegible] Neurology, General Hospital
[illegible] Dental Devices

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